



# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

|  |  |  |                      |
|--|--|--|----------------------|
| Applicant's or agent's file reference<br>P10349WO  | <b>FOR FURTHER ACTION</b>                                |  | See Form PCT/PEA/416 |
| International application No.<br>PCT/GB2005/000223   | International filing date (day/month/year)<br>24.01.2005 | Priority date (day/month/year)<br>23.01.2004   |                      |
| International Patent Classification (IPC) or national classification and IPC<br>A61M5/20, A61M5/30   |  |  |                      |
| Applicant<br>THE MEDICAL HOUSE PLC et al.  |  |  |                      |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 7 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> |  |  |                      |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>   |  |  |                      |
| Date of submission of the demand<br><br>20.10.2005   |  | Date of completion of this report<br><br>23.01.2006  |                      |
| Name and mailing address of the international preliminary examining authority:<br><br> European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465  |  | Authorized Officer<br><br>Reinbold, S<br><br>Telephone No. +49 89 2399-7918<br><br> |                      |

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2005/000223

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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-26 as originally filed

**Claims, Numbers**

1-32 received on 25.10.2005 with letter of 20.10.2005

**Drawings, Sheets**

1/27-27/27 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

|                               |             |      |
|-------------------------------|-------------|------|
| Novelty (N)                   | Yes: Claims | 1-32 |
|                               | No: Claims  |      |
| Inventive step (IS)           | Yes: Claims | 1-32 |
|                               | No: Claims  |      |
| Industrial applicability (IA) | Yes: Claims | 1-32 |
|                               | No: Claims  |      |

2. Citations and explanations (Rule 70.7):

**see separate sheet**

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item V**

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Reference is made to the following documents:

D1: US 6544234  
D2: WO 03097133  
D3: US 5681291  
D4: WO 0009186

**Novelty Article 33(2) PCT and Inventive Step Article 33(3) PCT**

2. The present application does appear to meet the criteria of Article 33(1) PCT, because the subject-matter of **claims 1-32** is new and inventive in the sense of Article 33(2) and (3) PCT.

The document D1 is regarded as being the closest prior art and discloses (the references in parentheses applying to this document) an injection device (10) comprising (figures 1-19) an outer housing (50) inside which is located:

- a barrel (12)
- a needle (18) at one end of the barrel, the needle (18) and barrel (12) being such that at least part of the needle is axially moveable in and out of said outer housing (50) but is biased to be normally wholly inside said housing
- a plunger (28)
- an inner housing (96) intermediate the outer housing and the barrel and plunger
- an energy source (94) in communication with said inner housing (96)
- wherein the inner housing (96) is moveable by the energy source between three positions, namely:
  - a first position (Fig.4) in which the inner housing has one or more radially flexible tags (100) which are in communication with the barrel (30+36) such that, in use, the plunger and barrel are moveable axially so as to move at least part of said needle out of the outer housing
  - a second position in which said plunger is moveable axially into said barrel so as to expel medicament through the needle

- a third position in which the plunger and barrel are able to retract in order to retract the needle into the outer housing

The subject-matter of claim 1 therefore differs from this known device in that:

- the inner housing is moveable between three positions, namely:
  - a second position in which the inner housing has one or more radially flexible tags which are in communication with the plunger but not the barrel
  - a third position in which said one or more radially flexible tags on the inner housing are in communication with neither the barrel nor the barrel

The problem to be solved by the present invention may therefore be regarded as how to retract in an alternative way the needle into the outer housing after the injection.

No document of the search report discloses a such injection device.

The document D2 discloses an injection device with a retractable needle but without a driving force applied to the flange of the syringe. It is not evident to combine the teachings of D1 and D2 in order to make a retractable needle with several flexible tags in D1.

The subject matter of **claims 1-32** is considered to meet the requirement of Article 33 (1) PCT in respect of novelty and inventive step.

#### **Re Item VII**

#### **Certain defects in the international application**

1. Claim 32 contains references to the drawings. According to Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is not the case here.
2. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the **relevant background art** disclosed in the documents D1 is not mentioned in the description, nor are these documents identified therein.

**Re Item VIII**

**Certain observations on the international application**

Although **claims 1,29 and 30** have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought.

The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection. Hence, these claims do not meet the requirements of Article 6 PCT.

It appears to be appropriate to file an amended set of claims taking account of the above comments and Article 34(2)(b) PCT. The relevant subject-matter should be defined in a single independent claim followed by dependent claims covering features which are merely optional (Rules 6.3 and 6.4 PCT)